Policy Statement

The use of dynamic spinal visualization is considered *investigational*.

Vertebral motion analysis is considered *investigational*.

Policy Guidelines

The following CPT codes are specific for these techniques:

- **76120**: Cineradiography/videoradiography, except where specifically included
- **76125**: Cineradiography/videoradiography to complement routine examination (List separately in addition to code for primary procedure)

Cineradiography/videofluoroscopy can be used once per anatomic area with modifier -59 (distinct procedural service) appended to the code when it is used for additional anatomic regions.

These procedures have both a technical and a professional component.

There is no specific code for vertebral motion analysis and some dynamic spinal visualization techniques. In such circumstances, refer to the unlisted codes in the Codes table.

Description

Dynamic spinal visualization is a general term addressing different imaging technologies that simultaneously visualize spine (vertebrae) movements and external body movement. Vertebral motion analysis uses similar imaging as dynamic spinal visualization, with the addition of controlled movement and computerized tracking. These technologies have been proposed for the evaluation of spinal disorders including neck and back pain.

Related Policies

- Positional Magnetic Resonance Imaging

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.
Regulatory Status

In 2012, the KineGraph VMA™ (Vertebral Motion Analyzer; Ortho Kinematics) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (k133875). The system includes a Motion Normalizer™ for patient positioning, standard fluoroscopic imaging, and automated image recognition software. Processing of scans by Ortho Kinematics is charged separately. Food and Drug Administration product code: LLZ.

Rationale

Background

Flexion/Extension Radiography

Dynamic spinal visualization and vertebral motion analysis are proposed for individuals who are being evaluated for back or neck pain and are being considered for standard flexion/extension radiographs. Flexion/extension radiographs may be performed with a passive external force or by the patient's own movement. Typically, radiographs are taken at the end ranges of flexion and extension and the intervertebral movements (rotation and translation) are measured to assess spinal instability. Flexion/extension radiographs may be used to assess radiographic instability in order to diagnose and determine the most effective treatment (e.g., physical therapy, decompression, or spinal fusion) or to assess the efficacy of spinal fusion.

Dynamic Spinal Visualization

Digital Motion X-Ray

Most spinal visualization technologies use x-rays to create images either on film, video monitor, or computer screen. Digital motion x-ray involves the use of film x-ray or computer-based x-ray "snapshots" taken in sequence as a patient moves. Film x-rays are digitized into a computer for manipulation, while computer-based x-rays are automatically created in a digital format. Using a computer program, the digitized snapshots are then sequenced and played on a video monitor, creating a moving image of the inside of the body. This moving image can then be evaluated by a physician alone or by using computer software that evaluates several aspects of the body's structure, such as intervertebral flexion and extension, to determine the presence or absence of abnormalities.

Videofluoroscopy and Cineradiography

Videofluoroscopy and cineradiography are different names for the same procedure, which uses fluoroscopy to create real-time video images of internal structures of the body. Unlike standard x-rays, which take a single picture at one point in time, fluoroscopy provides motion pictures of the body. The results of these techniques can be displayed on a video monitor as the procedure is being conducted, as well as recorded, to allow computer analysis or evaluation at a later time. Like digital motion x-ray, the results can be evaluated by a physician alone or with the assistance of computer software.

Dynamic Magnetic Resonance Imaging

Dynamic MRI is also being developed to image the cervical spine. This technique uses an MRI-compatible stepless motorized positioning device and a real-time true fast imaging with steady-state precession sequence to provide passive kinematic imaging of the cervical spine. The quality of the images is lower than a typical MRI sequence but is proposed to be adequate to observe changes in the alignment of vertebral bodies, the width of the spinal canal, and the spinal cord. Higher-resolution imaging can be performed at the end positions of flexion and extension.

Vertebral Motion Analysis

Vertebral motion analysis systems like the KineGraph VMA (Vertebral Motion Analyzer) provide assisted bending with fluoroscopic imaging and computerized analysis. The device uses facial recognition software to track vertebral bodies across the images. Proposed benefits of the...
vertebral motion analysis are a reduction in patient-driven variability in bending and assessment of vertebral movement across the entire series of imaging rather than at the end range of flexion and extension.

**Literature Review**
Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

**Dynamic Spinal Visualization**
**Clinical Context and Test Purpose**
The purpose of dynamic spinal visualization is to determine whether the abnormal movement of the spine contributes to neck or back pain. This would inform clinical decision making about the appropriate intervention, either physical therapy or surgery.

The question addressed in this evidence review is: Does the use of dynamic spinal visualization provide additional information beyond that obtained with conventional imaging technology and does this additional information improve health outcomes?

The following PICO was used to select literature relevant to the review.

**Patients**
The relevant population of interest is individuals being evaluated for back or neck pain.

**Interventions**
The test being considered is dynamic spinal visualization, which is administered in an outpatient setting.

**Comparators**
The following tests are currently being used to make decisions about managing abnormal movement contributing to back and neck pain: conventional radiography and magnetic resonance imaging (MRI), which are administered in an outpatient setting.

**Outcomes**
The outcomes of interest are whether dynamic spinal visualization leads to new findings and whether these findings improve health outcomes, including pain and function. Timing of short-term outcomes is after completion of physical therapy or surgery.

**Study Selection Criteria**
For the evaluation of the clinical utility of dynamic spinal visualization, studies would need to use the technology as either an adjunct or a replacement to current tests being used to make decisions about managing abnormal movement in patients with neck and back pain. Outcomes would be symptoms and functional outcomes.

In the absence of direct evidence for the clinical utility of dynamic spinal visualization, evidence for clinical validity is evaluated, in which we can make inferences on clinical utility. Below are selection criteria for studies to assess clinical validity:
- The study population represents the population of interest. Eligibility and selection are described.
• The test is compared with a credible reference standard.
• If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
• Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristics [ROC], area under ROC curve [AUROC], c-statistic, likelihood ratios) may be included but are less informative.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

**Clinically Valid**
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

As of the most recent literature update, the evidence on dynamic spinal visualization remains predominantly comparisons of spine kinetics in patients with neck or back pain to healthy controls.

**Systematic Reviews**
A systematic review by Xu et al (2017) reviewed 13 studies on dynamic supine MRI for patients with cervical spondylotic myelopathy, although it appears that the studies evaluated flexion/extension images rather than continuous motion.1

**Case-Control Studies**
Teyhen et al (2007) compared 20 patients with lower back pain to 20 healthy controls to provide construct validity for a clinical prediction rule that would identify patients likely to benefit from stabilization exercises,2 while Ahmadi et al (2009) used digital videofluoroscopy to compare 15 patients who had lower back pain with 15 controls to refine criteria for diagnosing lumbar segmental instability.3

**Clinically Useful**
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

**Direct Evidence**
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No RCTs were identified that support the clinical utility of dynamic spinal visualization for this population.

The literature evaluating the clinical utility of dynamic spinal visualization techniques, including digital motion x-ray and cineradiography (videofluoroscopy) for the evaluation and assessment of the spine, is limited to a few studies involving small numbers of participants.4,5,6 No evidence was identified to indicate that clinical use improves health outcomes.

**Chain of Evidence**
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.
Because the clinical validity of dynamic spinal visualization has not been established, a chain of evidence cannot be constructed.

**Section Summary: Dynamic Spinal Visualization**
The literature evaluating the clinical utility of dynamic spinal visualization techniques, including digital motion x-ray and cineradiography (videofluoroscopy) and dynamic MRI, for the evaluation and assessment of the spine, is limited to a few studies involving small numbers of participants. The available studies have compared spine kinetics in patients who had neck or back pain with that in healthy controls. No literature was identified on the diagnostic accuracy of dynamic visualization in a relevant patient population. No evidence was identified to indicate that clinical use improves health outcomes such as symptoms or function.

**Vertebral Motion Analysis**

**Clinical Context and Test Purpose**
The purpose of VMA is to determine whether the abnormal movement of the spine contributes to neck or back pain. This would inform clinical decision making about the appropriate intervention, either physical therapy or surgery. VMA might also be used to assess the success of fusion.

The question addressed in this evidence review is: Does the use of VMA provide additional information beyond that obtained with conventional imaging technology and does this additional information improve health outcomes?

The following PICO was used to select literature relevant to the review.

**Patients**
The relevant population of interest is individuals who are being evaluated for back or neck pain and are being considered for standard flexion/extension radiographs.

**Interventions**
The test being considered is VMA, which is administered in an outpatient setting.

**Comparators**
The following tests are currently being used to make decisions about managing abnormal movement contributing to back and neck pain: conventional radiography and MRI, which are administered in an outpatient setting.

**Outcomes**
The outcomes of interest are whether VMA leads to new findings and whether these findings improve health outcomes, including pain and function. Timing of short-term outcomes is after completion of physical therapy or surgery.

**Study Selection Criteria**
For the evaluation of the clinical utility of VMA, studies would need to use the technology as either an adjunct or a replacement to current tests being used to make decisions about managing abnormal movement in patients with neck and back pain. Outcomes would be symptoms and functional outcomes.

In the absence of direct evidence for the clinical utility of VMA, evidence for clinical validity is evaluated, in which we can make inferences on clinical utility. Below are selection criteria for studies to assess clinical validity:

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., ROC, AUROC, c-statistic, likelihood ratios) may be included but are less informative.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

**Clinically Valid**
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Cheng et al (2016) and Yeager et al (2014) reported that VMA decreased variability in the measurement of lumbar spinal movement compared with a digitized manual technique.\(^7,8\) Diagnostic performance of VMA was reported by Davis et al (2015) in a retrospective study of 509 symptomatic patients and 73 asymptomatic participants.\(^9\) The comparator was rotational and translational movement from flexion/extension radiographs. The investigators considered instability in symptomatic patients to be true-positive and instability in asymptomatic participants as false-positive, leading to reported differences in diagnostic accuracy between standard flexion/extension radiographs and VMA. In the absence of a true reference standard, the interpretation of this study is limited.

**Clinically Useful**
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

**Direct Evidence**
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs were identified that support the clinical utility of VMA in this population.

**Chain of Evidence**
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the clinical validity of VMA has not been established for this indication, a chain of evidence cannot be constructed.

**Section Summary: Vertebral Motion Analysis**
Three studies with overlapping authors have been identified on VMA. These studies have reported that VMA reduces variability in the measurement of rotational and translational spine movement compared with standard flexion/extension radiographs. One study reported an improvement in diagnostic accuracy compared with flexion/extension radiographs, but the interpretation of this study is limited by the lack of a true reference standard.

**Summary of Evidence**
For individuals who have neck or back pain who receive dynamic spinal visualization, the evidence includes comparative trials. Relevant outcomes are test accuracy, symptoms, and functional outcomes. Techniques include digital motion x-rays, cineradiography / dynamic magnetic resonance imaging of the spine and neck. The available studies compare spine kinetics in patients who had neck or back pain with that in healthy controls. No literature
was identified on the diagnostic accuracy of dynamic visualization in a relevant patient population. No evidence was identified on the effect of this technology on symptoms or functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have back or neck pain who receive vertebral motion analysis, the evidence includes comparisons to standard flexion/extension radiographs. Relevant outcomes are test accuracy, symptoms, and functional outcomes. These studies reported that vertebral motion analysis reduces variability in measurement of rotational and translational spine movement compared with standard flexion/extension radiographs. Whether the reduction in variability improves diagnostic accuracy or health outcomes is uncertain. The single study that reported on diagnostic accuracy lacked a true criterion standard, limiting interpretation of findings. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Supplemental Information**

**Practice Guidelines and Position Statements**
No guidelines or statements were identified.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in July 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

**References**

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

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<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
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<th>Effective Date</th>
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<tr>
<td>03/30/2015</td>
<td>BCBSA Medical Policy adoption</td>
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<tr>
<td>12/30/2016</td>
<td>Policy revision without position change</td>
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<td>05/07/2017</td>
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<td>Policy title change from Dynamic Spinal Visualization</td>
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<td>11/01/2020</td>
<td>Annual review. No change to policy statement. Literature review updated.</td>
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Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance
with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.